

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

**IN RE: TESTOSTERONE REPLACEMENT
THERAPY PRODUCTS LIABILITY
LITIGATION**

**Case No. 1:14-cv-1748
MDL No. 2545**

Hon. Matthew F. Kennelly

THIS DOCUMENT RELATES TO:

All Cases Listed in Exhibit A to Motion

**DEFENDANTS AUXILIUM PHARMACEUTICALS, INC.;
PFIZER INC.; AND PHARMACIA & UPJOHN COMPANY, LLC'S
MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR ENTRY OF
FINAL JUDGMENT AND PARTIAL FINAL JUDGMENT PURSUANT TO
FEDERAL RULES OF CIVIL PROCEDURE 54(b) AND 58**

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I. INTRODUCTION

On November 9, 2015, this Court issued a Memorandum Opinion and Order (Dkt. No. 1051) dismissing all claims against Defendants Pfizer Inc., Pharmacia & Upjohn Company, LLC (the “Pfizer Defendants”), and Auxilium Pharmaceuticals, Inc. (“Auxilium”) (collectively, the “ANDA Defendants”) related to their testosterone replacement therapy (“TRT”) medications, Depo-Testosterone and Testopel (the “ANDA TRT products”), which the Food and Drug Administration (“FDA”) approved pursuant to abbreviated new drug applications (“ANDAs”). In doing so, the Court rightly held that all of Plaintiffs’ claims related to the ANDA TRT products are preempted.

The ANDA Defendants now respectfully ask the Court to enter final judgment in their favor with respect to the preempted claims. Under the circumstances presented here, entry of a separate document, as required by Rule 58, is all that is required to resolve the 515 cases currently on file in which Plaintiffs have sued one or more ANDA Defendant(s) (but no other defendant) and only allege that they used Depo-Testosterone and/or Testopel (but no other TRTs) (“the ANDA-only cases”).¹ There is no reason for the Court to refrain from entering final judgment in those cases.

Plaintiffs also have filed an additional 244 cases against at least one of the ANDA Defendants as well as at least one Defendant who manufactures a TRT product approved through FDA’s full new drug application (“NDA”) process, such that Plaintiffs have alleged use of at least one ANDA TRT and at least one NDA TRT (“the mixed ANDA / NDA cases”).² For these

¹ These ANDA-only cases are identified in Exhibit B to the ANDA Defendants’ motion.

² In addition to Testopel, Auxilium also manufactures Testim, which FDA approved pursuant to an NDA. By this motion, Auxilium seeks the entry of partial final judgment only on claims asserted against it relating to Testopel; Auxilium does not seek partial judgment on any non-Testopel claims asserted against it. All of the mixed ANDA / NDA cases, including those filed

mixed ANDA / NDA cases, entry of partial final judgment on behalf of the ANDA Defendants pursuant to Federal Rule of Civil Procedure 54(b) is appropriate because the dismissed claims against the ANDA Defendants are separate for purposes of Rule 54, and there is no just reason to delay entry of judgment as to those dismissed claims. Further, entry of partial final judgment will promote judicial economy and serve the interests of justice because all Plaintiffs subject to the Court's Order—should any wish to appeal—may file a consolidated appeal, thereby resolving this threshold legal issue for all affected Plaintiffs at one time, rather than having the Plaintiffs in the ANDA-only cases appeal now but requiring the Plaintiffs in the mixed ANDA / NDA cases to appeal, if ever, years from now, when their claims against the NDA Defendants also are resolved. Thus, the Court should grant the ANDA Defendants' motion and enter final judgment in all the ANDA-only cases and partial final judgment on behalf of the ANDA Defendants with regard to their ANDA TRT products in the mixed ANDA / NDA cases.³

II. THE COURT SHOULD ENTER FINAL JUDGMENT IN THE ANDA-ONLY CASES AND PARTIAL FINAL JUDGMENT IN THE MIXED ANDA / NDA CASES.

Rule 58 requires entry of a separate judgment for claims dismissed, as here, pursuant to Rules 12(b)(6) and 12(c). That is the only step required to resolve the ANDA-only cases, thereby beginning the time for Plaintiffs to appeal, if any should so choose. The Pfizer

against the Pfizer Defendants and those filed against Auxilium involving Testopel, are identified in Exhibit C to the ANDA Defendants' motion.

³ Prior to filing this motion, the ANDA Defendants submitted to the Plaintiffs' Steering Committee ("PSC") a list pursuant to Case Management Order No. 26 ("CMO 26"), which identified the cases subject to the Court's November 9, 2015 Order (including both the ANDA-only cases and the mixed ANDA / NDA cases) to obtain agreement on which individual cases and claims should be dismissed pursuant to that Order. The PSC responded with a blanket objection as to each claim on that CMO 26 list and informed the ANDA Defendants that the PSC intends to move for reconsideration and/or clarification of the Court's Order. The parties then agreed to file their motions simultaneously and present the Court with a proposed briefing schedule on the motions at the January 2016 status conference.

Defendants and Auxilium respectfully request that the Court take that step now and enter final judgment in all of the ANDA-only cases.

For the mixed ANDA / NDA cases, Rule 54(b) authorizes the entry of partial final judgment of individual parties where “there is no just reason for delay.” Fed. R. Civ. P. 54(b). Here, both the equities and considerations of judicial economy and administrative convenience warrant partial final judgment on behalf of the ANDA Defendants. Accordingly, the Court should grant the ANDA Defendants’ motion and enter final judgment in all of the ANDA-only cases and partial final judgment on all claims involving ANDA TRT products in the mixed ANDA / NDA cases.

A. For the ANDA-Only Cases, Rule 58 Requires Entry of a Separate Judgment.

Rule 58 of the Federal Rules of Civil Procedure requires that every judgment be set forth in a separate document. Fed. R. Civ. P. 58(a). There are certain exceptions to the Rule, but none applies here.⁴ *Id.* Accordingly, as directed by Rule 58(b), the ANDA Defendants respectfully ask that the Court enter a Rule 58 judgment on a separate document identifying the ANDA-only cases dismissed entirely by the Court’s November 9, 2015 Order.⁵ *See Perry v. Sheet Metal Workers’ Local No. 73 Pension Fund*, 585 F.3d 358, 362 (7th Cir. 2009) (reminding litigants that “if the court has not entered a proper Rule 58 judgment on a separate document, the parties should ask the court to do so”). For those cases, there is no reason the Court should refrain from entering final judgment.

⁴ A separate document is not required for a judgment under Rule 50(b); amending or making additional findings under Rule 52(b); an award of attorneys’ fees pursuant to Rule 54; a new trial or a decision altering or amending a judgment under Rule 59; or for relief under Rule 60. *Id.*

⁵ While Rule 58 requires a “separate document” for each case, the Court could issue a single document that lists the ANDA-only cases—*i.e.*, a final judgment with Exhibit B attached—and order the clerk’s office to enter that judgment in every case on the list.

B. Entry of Partial Final Judgment Pursuant to Rule 54(b) Is Appropriate in the Mixed ANDA / NDA Cases.

Rule 54 states that “[w]hen an action presents more than one claim for relief . . . or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay.” Fed. R. Civ. P. 54(b); *see also Gelboim v. Bank of Am. et al.*, -- US --, 135 S. Ct. 897, 906, (2015) (holding, in a case involving a MDL proceeding, that certification of partial final judgment pursuant to Rule 54(b) is proper to “permit acceleration of appeals in multiple-claim cases”).⁶ In addition to determining that there is no just reason for delay, the Seventh Circuit also has held that a district court must determine that the claims for which partial final judgment are sought are “separate” for purposes of Rule 54. As shown below, both requirements are met here.

1. Plaintiffs’ Claims Involving the ANDA Defendants Are “Separate” for Purposes of Rule 54(b).

In determining whether a partial final judgment is properly entered under Rule 54(b), the Seventh Circuit first requires consideration of whether the dismissed and retained claims are separate. Where, as here, critical “facts underlying different claims are different, the claims are separate for Rule 54(b) purposes.” *Jack Walters & Sons Corp. v. Morton Bldg., Inc.*, 737 F.2d 698, 702 (7th Cir. 1984). Even if claims “arise from the same event or occurrence, they may be separable for Rule 54(b) purposes if they rely on entirely different legal entitlements yielding

⁶ In *Gelboim*, the Supreme Court further clarified that “[c]ases consolidated for MDL pretrial proceedings ordinarily retain their separate identities.” -- US --, 135 S. Ct. at 905. Thus, if a case within an MDL proceeding is dismissed in its entirety, the losing party may take an immediate appeal as of right. If a case within an MDL proceeding involves multiple parties or multiple claims and fewer than all claims against all parties are dismissed, such as the mixed ANDA/NDA cases here, Rule 54(b) applies to those individual cases. *Id.* at 905-06.

separate recoveries.” *Marseilles Hydro Power, LLC v. Marseilles Land and Water Co.*, 518 F.3d 459, 464 (7th Cir. 2008).

For example, in *Marseilles Hydro Power, LLC*, 518 F.3d 459, the dismissed claims pending before the appellate court and the claims retained by the district court all stemmed from the same event—the collapse of a retaining wall in 2000—but the Seventh Circuit nevertheless found that entry of partial final judgment was proper. *Id.* at 464-65. The Court concluded that because the claims against one of the several defendants had been resolved (like all of the claims with respect to the ANDA TRT products here), those claims were ripe for appellate review. *Id.* In other contexts, the Seventh Circuit has held that “[a]n order that disposes finally of a claim against one party to the suit can be certified for an immediate appeal under [Rule 54(b)] even if identical claims remain pending between the remaining parties.” *Nat’l Metalcrafters, a Div. of Keystone Consol. Indus. v. McNeil*, 784 F.2d 817, 821 (7th Cir. 1986) (emphasis added).

In the mixed ANDA / NDA cases, the dismissed and retained claims are separate because the “facts underlying [the] different claims are different,” *Jack Walters & Sons Corp.*, 737 F.2d at 702, and the claims rely on “different legal entitlements yielding separate recoveries.” *Marseilles Hydro Power, LLC*, 518 F.3d at 464. As the Court noted in its November 9, 2015 Order, Plaintiffs’ claims against the ANDA Defendants are different factually because FDA approved the TRTs manufactured by the ANDA Defendants pursuant to the ANDA process, whereas FDA approved the TRTs manufactured by the NDA Defendants pursuant to the NDA process. And the applicable law that flows from that factual difference—the preemption standard applicable to ANDA TRT products as compared to the preemption standard applicable to NDA TRT products—also is different. As a result, any appeal of the Court’s November 9, 2015 Order will address questions regarding the federal preemption of claims against ANDA

holders that simply will not be relevant to any later appeal involving the NDA Defendants. Plaintiffs' claims against the ANDA Defendants therefore are "separate" from their claims against the NDA Defendants for purposes of Rule 54(b).

2. There Is No Just Reason to Delay Entry of Partial Final Judgment.

Next, to enter partial final judgment, the Court also must find that there is "no just reason to delay." Fed. R. Civ. Pro. 54(b). In doing so, the Court should consider "judicial administrative interests as well as the equities involved. . . . [including] whether the claims under review were separable from the others remaining to be adjudicated and whether the nature of the claims already determined was such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals." *Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 8 (1980).

Here, the equities counsel in favor of entry of partial final judgment, for both sides. Without entry of partial final judgment in the mixed ANDA / NDA cases, the ANDA Defendants will sit in a state of limbo (possibly for years) until the claims against the NDA Defendants are litigated to final judgment regarding all of Plaintiffs' claims. The ANDA Defendants are entitled to know when the cases against them are over. *See Nat'l Metalcrafters*, 784 F.2d at 821 ("[The defendant] doesn't have to wait till the end of what may be protracted proceedings in the district court to find out for sure whether he is, as the district court found, not violating any rights of the plaintiff.").

Because the claims against them have been dismissed entirely, the ANDA Defendants also should be relieved of the burden and expense of having to participate in the ongoing MDL. Without entry of partial final judgment, however, the ANDA Defendants would have to remain involved. This is just the kind of inequity Rule 54(b) is intended to prevent. *See Payne v. Massachusetts*, No. 09-10355-RWZ, 2011 WL 7768629, at *3 (D. Mass. Nov. 15, 2011)

(finding no just reason for delay in granting partial final judgment to dismissed defendants because it would “impose a significant burden” on them to remain in the case and noting further that “if an appeal establishes that the case should not have been dismissed, then that issue should be decided soon so that the defendants can participate in any discovery”). By contrast, entry of partial final judgment will enable the Court and the remaining litigants to focus on the claims asserted against the remaining Defendants.

Likewise, refraining from entering partial judgment would be unfair to a significant number of Plaintiffs. Absent entry of partial final judgment, Plaintiffs in the ANDA-only cases will be able to appeal immediately (if any so choose), whereas Plaintiffs in the mixed ANDA / NDA cases will not be able to appeal until their claims against the NDA Defendants are resolved. Those mixed ANDA / NDA Plaintiffs, like the ANDA Defendants, are entitled to know whether their claims against the ANDA Defendants are viable at the conclusion of an immediate appeal, rather than being forced to wait for years to commence an appeal after their claims against the NDA Defendants also are resolved.

In addition to the equities, judicial administrative interests warrant the entry of partial final judgment as well. As described above, the claims against the ANDA Defendants are distinct from those of the NDA Defendants. If the Court enters both final judgment in the ANDA-only cases and partial final judgment in the mixed ANDA / NDA cases at the same time, the Seventh Circuit will not be presented with the same preemption issue more than once (should any Plaintiffs elect to appeal). On the other hand, if the Court enters final judgment in the ANDA-only cases now but does not enter partial final judgment in the mixed ANDA / NDA cases, it is likely that the Seventh Circuit “would have to decide the same issues more than once . . .” *Curtiss-Wright Corp.*, 446 U.S. at 8. That is so because Plaintiffs in the mixed ANDA /

NDA cases would have to wait to appeal their claims against the ANDA Defendants until they also have resolved their claims against the NDA Defendants, which very well may occur in piecemeal fashion over the course of this litigation. Rather than potentially require the Seventh Circuit to rule on this issue regarding ANDA TRT products repeatedly, the Court should enter judgment in both the ANDA-only and mixed ANDA / NDA cases now, so that the Seventh Circuit and the litigants can achieve finality, one way or the other.⁷

Finally, in the parties' discussions about the entry of final judgment, the PSC has asserted that entry of final judgment (or of partial final judgment) would require hundreds of Plaintiffs to file notices of appeal, which the PSC contends would be unwieldy. On that basis, the PSC has suggested that the Court should enter final judgment in only one case and stay entry of judgment in the remaining cases. But those administrative concerns are meritless. Under Federal Rule of Appellate Procedure 3(a)(1), Plaintiffs may take an appeal "by filing a notice of appeal with the district clerk" within the allowed time. Fed. R. App. Proc. 3(a)(1). Under that rule, the PSC could file a single combined notice of appeal with the district court clerk listing all the relevant cases—*i.e.*, those listed in Exhibit A—rather than hundreds of individual notices of appeal.

There also will be no obstacle to a consolidated appeal at the Seventh Circuit, as the Federal Rules of Appellate Procedure specifically contemplate "joint or consolidated appeals" where "two or more parties are entitled to appeal from a district-court judgment . . . and their interests make joinder practicable," in which case they can file a joint notice of appeal and "proceed on appeal as a single appellant." Fed. R. App. Proc. 3(b)(1). Thus, judicial administrative interests justify entering partial final judgment now in the mixed ANDA / NDA cases, rather than putting the cases involving the ANDA Defendants on multiple, separate tracks.

⁷ As with the ANDA-only cases, the Court could issue a single document that lists the mixed ANDA / NDA cases and order the clerk's office to enter that judgment in every case on the list.

In light of the above, there is no just reason to delay entry of final judgment on Plaintiffs' claims relating to the ANDA TRT products, and the Court should grant the ANDA Defendants' motion for entry of partial final judgment in the mixed ANDA / NDA cases.

III. CONCLUSION

For the foregoing reasons, the ANDA Defendants respectfully request that the Court enter final judgment with respect to the ANDA-only cases listed in Exhibit B pursuant to Rule 58 and enter partial final judgment with respect to the mixed ANDA / NDA cases listed in Exhibit C pursuant to Rule 54(b).

Date: December 22, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Matthew A. Holian, hereby certify that on December 22, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Matthew A. Holian